REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

As noted in the Office Action Summary, Claims 5-7 are pending. Claims 1-4, 8-12, and 16-37 have been canceled. Withdrawn Claims 13-15 have been amended. Applicants note with appreciation that the Examiner indicated in the Office Action that if Claims 5-7 were in allowable form, the rejoinder of process Claims 13-15 would be in order. Applicants submit that amended Claims 5-7 are now in allowable form, and requests that rejoinder of withdrawn, currently amended Claims 13-15 be permitted.

Claims 5-7 have been amended. Basis for the amendments may be found throughout the specification and claims as-filed, and no prohibited new matter is presented herein.

Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 5-7 stand rejected under 35 U.S.C. § 112, first paragraph, as the term "specifically" in Claim 5 is purportedly new matter. In the interest of expediating prosecution, Applicants have amended Claim 5 by deleting the word "specifically" from the claim. Thus, this rejection is moot.

Claim Rejections – 35 U.S.C. § 101

Claims 5 and 7 stand rejected under 35 U.S.C. § 101 because the claimed invention is purportedly directed to non-statutory subject matter. As recommended

by the Examiner, Claims 5 and 7 are amended to recite an "isolated antibody". Applicants submit that Claims 5 and 7 are now directed to statutory subject matter. Claims 6 and 13-15 are also amended in this regard. In light of the above, Applicants request that the objection under 35 U.S.C. § 101 be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claims 5-7 stand rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over Purnelle et al. (GenBank, Sequence Database Accession P25371, National Center for Biotechnology Information, National Library of Medicine, Bethesda, Maryland, publicly available May 1, 1992) or Kirby et al. (GenBank, Sequence Database Accession Q94960, National Center for Biotechnology Information, National Library of Medicine, Bethesda, Maryland, publicly available February 1, 1997) and further in view of Harlow et al. (Antibodies: A Laboratory Manual, Cold Spring Harbor Laboratory Press, 1988, p. 142). Applicants traverse.

Applicants note with appreciation the telephone conversation with Examiner to clarify the references used to reject Claims 5 to 7 under 35 U.S.C. § 103. In accordance with Examiner's instructions, Applicants have addressed the rejection first with respect to Purnelle and further in view of Harlow, and second, with respect to Kirby and further in view of Harlow. Applicants note that per Examiner's comments, the references Roitt et al. and Herbert et al. are used by the Examiner merely to clarify the disclosures of Purnelle, Kirby, and Harlow, and are not being used as cited references to reject any of the claims in the present invention. Applicants now turn to the cited references.

For a *prima facie* case of obviousness, the following three requirements must be met. First, the prior art relied upon, coupled with the knowledge generally

available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine the reference with another reference. Second, the proposed modification must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. Third, the prior art reference must teach or suggest all the limitations of the claims. The teachings or suggestions, as well as the expectation of success, must come from the prior art and not from applicant's disclosure. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991); and *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Applicant respectfully submits that these criteria have not been met in the present Office Action.

Taken together, Purnelle and Harlow, or Kirby and Harlow, fail to meet the requirements for a *prima facie* case of obviousness. The cited references fail to suggest any motivation for one skilled in the art to modify or combine the teachings disclosed therein. From the disclosures in Purnelle and Harlow, or Kirby and Harlow, a skilled artisan would not have a reasonable expectation of success to modify such disclosures therein to make the present invention. Further, the cited references fail to teach or suggest all of the limitations of the claims in the present invention. Each cited reference is addressed in detail below.

Purnelle and Harlow

Purnelle et al. purportedly disclose a sequence for a polypeptide with 30.5% identity to SEQ ID NO:1 over 643 amino acid residues. Applicants received only a copy of the sequence listing as listed on GenBank, and therefore is addressing only

the same. The Office Action states that the polypeptide sequence of Purnelle shares multiple sets of five or more consecutive amino acids that either share identity with or are conservative substitutions for amino acids found in SEQ ID NO:1, a subset of which would be expected to comprise antibody epitopes shared with SEQ ID NO:1.

Harlow et al. is cited as a laboratory manual that purportedly discloses:

> [M]onoclonal antibodies are often more time-consuming and costly to prepare than polyclonal antibodies, and they are not necessarily the best choice for certain immunochemical techniques. In theory, either as single antibody preparations or as pools, monoclonal antibodies can be used for all of the tasks that require or benefit from the use of polyclonal antibodies. In practice, however, producing exactly the right set of monoclonal antibodies is often a difficult and laborious job (page 142).

Further, Harlow purportedly discloses immunochemical techniques for which polyclonal antibodies are usually good, including cell staining, immunoprecipitation and immunoblots.

Here, Purnelle and Harlow provide no information whatsoever as to the "particular form of the claimed invention or how to achieve it." *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 U.S.P.Q.2d 1741, 1743 (Fed. Cir. 1990). Further, Purnelle, taken alone, or in combination with Harlow, fail to disclose SEQ ID NO: 1, nor do either reference disclose an isolated antibody that binds to SEQ ID NO: 1.

Purnelle merely disclose a sequence listing and fails to teach monoclonal or polyclonal antibodies. Indeed, as the Office Action on page 6 concedes, Purnelle and Kirby "do not teach monoclonal, polyclonal antibody to SEQ ID NO:1." Harlow merely disclose that monoclonal antibodies are "often time-consuming and costly to prepare than polyclonal antibodies", but fail to teach monoclonal or polyclonal antibody to SEQ ID NO:1. Furthermore, Harlow does not provide the motivation

necessary under the prima facie obviousness analysis to bind antibodies to SEQ ID NO:1. The Federal Circuit, *In re Dow Chemical Co.*, instructs:

> The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art...Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure.

837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). The Court further explains:

> There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure.

837 F.2d at 473, 5 U.S.P.Q.2d at 1532. Because Purnelle merely discloses a sequence listing, and Harlow fails to disclose any procedure, any suggestion or motivation to bind monoclonal or polyclonal antibodies to SEQ ID NO:1, the *prima facie* case of obviousness cannot be satisfied.

The present invention does not identify anywhere in the disclosure any particular point of novelty of the SEQ ID NO:1 that would suggest to the skilled artisan that SEQ ID NO:1 would bind to monoclonal or polyclonal antibodies in the same manner as the sequences disclosed in Purnelle. Further, Harlow fails to remedy the deficiencies of Purnelle. Indeed, here, as in *Dow Chemical Co.*, "[o]f the many scientific publications cited ... none suggests that any process could be used successfully ... to produce this product having the desired properties." 837 F.2d at 473, 5 U.S.P.Q.2d at 1532. Thus, in this case, as in *Dow Chemical Co.*, the cited references do not satisfy the *prima facie* case of obviousness.

In numerous appeals, the Board of Patent Appeals and Interferences has held that even where a prior art reference discloses a residue with an 86% to 98% identity

with the claimed subject matter, the Board has still found the invention nonobvious and patentable over the prior art. *See Ex parte Kamboj et al.*, Consolidated Appeals, Appeal Nos. 1998-0217, 1999-2200, and 1999-2118.

In further support that Purnelle and Harlow fail to meet the requirements of a *prima facie* case of obviousness, Applicants refer to a document promulgated by the U. S. Patent and Trademark Office entitled, "Trilateral Project B3b: Mutual understanding in search and examination; Comparative study on biotechnology patent practices". In this document, ten case studies were presented. The U.S. Patent and Trademark Office ("Patent Office") provided a detailed analysis of whether each case study would comply with utility, enablement, and non-obviousness requirements in the United States.

Case 5 described a claim to an isolated polynucleotide that was 2400bp cDNA, and encodes a full-length protein of 800 amino acids. Specifically, Case 5 disclosed that a similarity search was performed using a known DNA and amino acid database and that the claimed polynucleotide showed 40% to 50% homology to the polynucleotide encoding a family of related proteins as described in prior art documents. The prior art search did not identify any sequence with over 50% similarity to the nucleotide sequence set forth in the isolated polynucleotide nor the full-length protein. In the Office's detailed analysis of Case 5, the Patent Office found that the prior art did not render the invention obvious, despite having a 40% to 50% similarity in nucleotide sequence. Further, the Patent Office stated that in the absence of a prior art disclosure teaching that additional proteins of the recited family of proteins are expected to exist, and absent a motivation to look for other nucleic acids encoding other members of the family of proteins in the same source material as that used by applicant, the invention would have been considered nonobvious to

the skilled artisan. If Examiner desires, Applicants are happy to provide copies of the case studies discussed above.

Although each situation must be examined on a case by case analysis, Applicants submit that a mere 30% identity, combined with a lack of teaching, disclosure, or suggestion in the prior art references to make the present invention, clearly establish that the invention would be non-obvious to the skilled artisan.

Kirby and Harlow

Kirby et al. purportedly disclose a sequence listing for a polypeptide with 32.1% identity to SEQ ID NO:1 over 643 amino acid residues. Applicants received only a copy of the sequence listing as listed on GenBank, and therefore is addressing only the same. The Office Action alleges that the polypeptide sequence of Kirby shares multiple sets of five or more consecutive amino acids that either share identity with or are conservative substitutions for amino acids found in SEQ ID NO:1, a subset of which would be expected to comprise antibody epitopes shared with SEQ ID NO:1.

As described *supra*, Harlow is a laboratory manual that purportedly discloses that monoclonal antibodies are often more time-consuming and costly to prepare than polyclonal antibodies, and that in practice, producing the right set of monoclonal antibodies is often a difficult and laborious job. Harlow further purportedly discloses immunochemical techniques for which polyclonal antibodies are usually good.

For the same reasons as described previously, the combined cited references of the sequence listing purportedly disclosed in Kirby, and further in view of the disclosures in Harlow, fail to meet the requirements of the prima facie obviousness test.

As with cited reference Purnelle, Kirby and Harlow likewise provide no disclosure whatsoever as to the "particular form of the claimed invention or how to achieve it." *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 U.S.P.Q.2d 1741, 1743 (Fed. Cir. 1990). Further, Kirby, taken alone or in combination with Harlow, fail to disclose SEQ ID NO: 1, nor do either disclose an isolated antibody that binds to SEQ ID NO:1.

Because Kirby merely disclose a sequence listing, and Harlow fails to disclose any procedure, any suggestion or motivation to bind monoclonal or polyclonal antibodies to SEQ ID NO:1, the *prima facie* case of obviousness cannot be satisfied. Here, as in *Dow Chemical Co.*, "[o]f the many scientific publications cited ... none suggests that any process could be used successfully ... to produce this product having the desired properties." Thus, in this case, as in *Dow Chemical Co.*, the cited references, taken alone or in combination, do not satisfy the *prima facie* case of obviousness.

The Cited References Fail to Establish a Prima Facie Case of Obviousness

The Federal Circuit has held that, "[a] general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out." *In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995). The fact that a general process can be conceived in advance for preparing an undefined sequence does not mean that a specifically claimed sequence could have been precisely envisioned and therefore obvious. Further, absent a specific teaching in the cited references that this particular SEQ ID NO:1 would bind similarly as the sequence as disclosed in Purnelle or Kirby to a monoclonal or polyclonal

antibody, the references fail to teach the present invention, and therefore cannot support a rejection under 35 U.S.C. § 103.

Because the disclosures present in the cited references could not have led the skilled artisan to have isolated this particular sequence SEQ ID NO:1, with these particular amino acids as claimed, the *prima facie* case of obviousness cannot be satisfied.

Additionally, no where in the specification of the present invention do Applicants identify any particular point of novelty of the SEQ ID NO:1 that would suggest to the skilled artisan that SEQ ID NO:1 would bind to monoclonal or polyclonal antibodies in the same manner as the sequences disclosed in Purnelle or Kirby. Further, Harlow fails to remedy the deficiencies of Purnelle and Kirby.

In conclusion, Applicants submit that the cited references, Purnelle, Kirby, or Harlow, alone or in combination, fail to meet the requirements for a *prima facie* case of obviousness. The cited references fail to contain any motivation to modify said references, fail to disclose each and every one of the elements in the presently claimed invention, and further lack any reasonable expectation of success should the references be so viewed.

In light of the above, Applicants respectfully submit that the rejection under U.S.C. § 103 be withdrawn.

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, a Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 838-6684 so that prosecution of the application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL PC
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